Remarks

This is a response to the rejections made in the Office Action dated September 25, 2001, which was designated as Final. A Notice of Appeal was filed on December 18, 2001. In lieu of filing an Appeal Brief at this time, and to attempt to expedite prosecution of this application, Applicants are filing herewith a Request for Continued Examination (RCE) and this Amendment and Response. A Petition for an Extension of Time has been also submitted herewith.

Claims 1-20 and 33 were rejected in the Office Action as allegedly being unpatentable over Bourzat et al. and Doble et al. in view of Novo Nordisk and Sandyk. Claim 1-20 and 33 have been cancelled, and therefore, this rejection with regard to claims 1-20 and 33 has been rendered moot.

Claims 34 and 35 have been presented and are directed to methods of alleviating stuttering, motor tic, clonic stuttering, dysfluency, speech blockage, dysarthria, Tourette's Syndrome or logospasm in a subject in need thereof, the method comprising administering a therapeutically effective dose of pagoclone, or a pharmaceutically acceptable salt thereof. Neither Bourzat et al. nor Doble et al. teach the use of pagoclone to treat stuttering, motor tic, clonic stuttering, dysfluency, speech blockage, dysarthria, Tourette's Syndrome or logospasm. Novo Nordisk and Sandyk have been cited in the Office Action to provide a mechanistic basis for the use of certain compounds to treat stuttering. However, neither Novo Nordisk nor Sandyk specifically states or suggests that the compound pagoclone can be used to treat stuttering. Moreover, it is not apparent from Novo Nordisk or Sandyk that a chemical compound could be used to treat stuttering even if the proposed mechanism is correct. For example, the title of the Sandyk document is "Resolution of of Dysarthria in Multiple Sclerosis with Weak Electromagnetic Fields." There are many examples in the literature where a mechanistic basis for a disease is proposed, but compounds that are known to play a role in the proposed mechanism do not show any therapeutic effect. It would indeed be wonderful if once a mechanism is proposed (provided that the proposed mechanism is correct) that a treatment could immediately be envisioned. Unfortunately, that is not the case. Thus, the Examiner has not made a *prima facie* case of obviousness with regard to the use of pagoclone to treat suttering since there is no reasonable expectation that the particular compound pagoclone could be used to treat

stuttering. A reasonable expectation of success is one of the basic considerations in determining obviousness or not. See MPEP, 8th Edition, Chapter 2141, page 2100-114, under the title "Basic Considerations Which Apply to Obviousness Rejections", specifically, point (D) which states: "Reasonable expectation of success is the standard with which obviousness is determined." All that the Examiner has done is made a case for "obvious to try", which is not the standard for obviousness, as the Court of Appeals for the Federal Circuit has made clear. See, for example, *Gillette Co. v. S.C. Johnson & Son*, 16 USPQ2d 1923 (Fed. Cir. 1990). Thus, the use of pagoclone to treat stuttering, motor tic, clonic stuttering, dysfluency, speech blockage, dysarthria, Tourette's Syndrome or logospasm is not obvious over Bourzat et al. and Doble et al. in view of Novo Nordisk and Sandyk, and this rejection should be withdrawn.

Applicant believes that in view of the amendments and remarks made above, claims 34 and 35 are in condition for allowance. Reconsideration and allowance of claims 34 and 35 is respectfully requested.

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